

**REMARKS**

Claims 1-46 are pending in the instant application. The application was previously subject to a Restriction Requirement to which Applicants responded by electing to prosecute Group I out of a three way Restriction. The Examiner has reevaluated the subject matter of the elected invention and has determined that the claims should be subject to another Restriction Requirement under 35 U.S.C. §121. In response to the second Restriction Requirement in Paper No. 8, Applicants hereby provisionally elect, with traverse, Group 1, wherein the primary genetic defect is an underexpression or lack of expression of the p53 gene, corresponding to the subject matter of Claim 1(a).

This provisional election is made without prejudice, it being understood that the applicants' right to the filing of one or more divisional applications directed to the non-provisionally elected subject matters is retained.

The Examiner requires restriction of the claims to one of the following invention groups:

Groups 1-52: Claims 1-20 and 23-25, drawn to methods of identifying secondary drug targets and using the identified secondary drug targets to screen candidate drug compounds.

Groups 53-101: Claims 21-22 and 30-46, drawn to compositions and methods of treating cancer wherein the active ingredient interferes with the expression or activity of a secondary drug target.

Group 102-144: Claims 26-29, drawn to pharmaceutical compositions comprising a mutated form of a secondary drug target.

Applicants note that the Examiner has stated that Claim 1 as filed links the invention of proposed Groups 1-52. Applicants note that such a linked set of claims and subject matter

were indeed previously elected by Applicants in their previous response dated September 13, 2002 (Paper No. 7).

Applicants further note that the Examiner has stated that upon allowance of Claim 1, the restriction requirement between Examiner's Groups 1-52 will be withdrawn and any claims depending from or otherwise including the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants respectfully submit that a Restriction Requirement that is dependent on the unpatentability of a broader linking claim would indicate that a search of the subject matter of all of Groups 1-52 would not be an undue burden on the Examiner.

Applicants also respectfully note that the research in the area of treating diseases by modulating the expression or activity of a secondary biological target (in particular a secondary biological target that may not have aberrant expression or activity and may not be the cause of the disease) has taken place only in the last ten (10) years prior to the earliest priority date accorded the instant application. Applicants therefore respectfully contend that a search of the scientific and patent art in the ten years prior to November 6, 1998 (the filing date of the international application of which this application is the U.S. national phase application), for any disclosure of secondary gene drug targeting or synthetic lethal drug targeting should be comprehensive with respect to the invention as originally claimed, yet would clearly not be an undue burden on the Examiner.

Applicants respectfully note that MPEP Section 803 provides:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed; and
- (2) There must be a serious burden on the examiner if restriction is not required.

As the Examiner is aware, a restriction requirement is proper when the claimed inventions are independent or distinct and when there is a serious burden on the Examiner to search the subject matter covered by the instant claims. See Section 803 of the Manual of Patent Examining Procedure. It is respectfully submitted that the Examiner has made no such showing of a serious burden. In view of the Examiner's lack of a demonstrable undue burden of search, Applicants respectfully submit that the provisional election of Group 1, wherein the primary genetic defect is an underexpression or lack of expression of the p53 gene, corresponding to the subject matter of Claim 1(a) is therefore not necessary.

Moreover, because there would be no serious burden on the Examiner in searching such a narrowly defined invention in such a recently initiated area of research, Applicants respectfully submit that the present restriction requirement is improper and should be withdrawn. Applicants respectfully submit that the Restriction Requirement dated August 20, 2002 previously set forth in Paper No. 6 should be re-entered and the election of Group 1 made on September 13, 2002 (Paper No. 7) be reinstated.

In view of the above, Applicants respectfully submit that the Examiner's "Restriction Requirement has been addressed and obviated by the above remarks, and that Claims 1-20, 23-25 are allowable and an early Notice of Allowance is earnestly solicited. If a telephonic communication with Applicants' representative will aid in the advancement of the prosecution of this application, please telephone the representative indicated below.

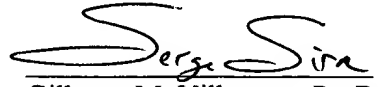
#### **CONCLUSION**

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

  
Gilberto M. Villacorta, PH.D.  
Registration No. 34,038  
Serge Sira, PH.D.  
Registration No. 39,445

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street, Suite 1600  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061

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